IMPLANTABLE DEVICE FASTENING SYSTEM AND METHODS OF USE

BACKGROUND OF THE INVENTION

1. FIELD OF THE INVENTION

The present invention relates to the fields of implantable medical devices and surgical instruments and fasteners. The present invention encompasses methods of fastening devices or implants in surgical procedures and the surgical fasteners and instruments used in the process.

2. DESCRIPTION OF THE RELATED ART

Surgical fasteners such as staples, clips, clamps, bands, tacks, or other wound or incision closure devices are commonly used in surgical procedures to allow a surgeon to fasten, secure and/or repair body tissue. Examples of surgical fasteners are given in U.S. Pat. Nos. 4,994,073 or 4,950,284 or 4,934,364 and 4,932,960.

Surgical fasteners have been used in surgical procedures to eliminate the need for suturing, which is both time consuming and inconvenient. In these applications the surgeon often uses a fastener implanting device loaded with one or more surgical fasteners to accomplish in a few seconds what would have taken many minutes to perform by suturing. This reduction in operating time reduces blood loss and trauma to the patient.

Typically, such fastening systems have been used mainly for the closure of incisions or wounds, or to fasten tissues together. A surgical fastening system that could be used with a number of types of implantable devices would be beneficial for surgeons. Currently, surgical devices that incorporate fastening systems often use extremely specialized systems that may be unnecessarily complicated and are unsuitable for adaptation to other applications. As a result, the majority of implantable devices are secured with sutures. For example, when inserting a gastric band and the associated access port, the port is sutured into place with 4 to 5 sutures against the rectus muscle sheath. Such placement of the sutures is often challenging because the ports are placed below several inches of fat, and suturing the port often takes as long as placing the band itself. An improved fastening system would allow easy, one-step attachment with security equivalent to the sutured device.

The present invention overcomes such problems in the art.

SUMMARY OF THE INVENTION

The present invention encompasses surgical fastening systems wherein an implantable device either contains a plurality of fasteners in pre-deployment position, or wherein an implantable device may have a housing fitted over the device, wherein the housing contains a plurality of fasteners in pre-deployment position. Accordingly, the present invention also encompasses a deployment system that optionally positions the implantable device, and which causes the fasteners to move into post-deployment position.

BRIEF DESCRIPTION OF THE DRAWINGS

The above objects and advantages of the present invention will be more fully understood by reference to the following description and annexed drawings, in which:

Figure 1 is an elevation view of a radial pivot fastener with staples in pre-deployment position;

Figure 2 is an elevation view of the radial pivot fastener of Figure 1 with staples in deployed position;

Figure 3 is a detail elevation view of the radial pivot fastener of Figure 1 with staples in pre-deployment position;

Figure 4 is a detail elevation view of the radial pivot fastener of Figure 2 with staples in deployment position;

Figure 5 is an elevation view of a delivery system;

Figure 6 is a cutaway view of the delivery system shown in Figure 5 and a port fastener;

Figure 7 is a detail cutaway elevation view of the distal end of the delivery system of Figure 6 and a port fastener in pre-deployment position;

Figure 8 is a detail cutaway elevation view of the distal end of the delivery system of Figure 6 and a port fastener in deployment position;

Figure 9 is an elevation view of a pencil grip handle configuration for a delivery system;

Figure 10 is a detail cutaway elevation view of the handle of the delivery system of Figure 9 shown in a starting position;

Figure 11 is a detail cutaway elevation view of the handle of the delivery system of Figure 9 shown in a fired position;

Figure 12 is an elevation view of a pistol grip handle configuration for a delivery system;

Figure 13 is a detail elevation view of the handle of the delivery system of Figure 12 shown in a starting position;

Figure 14 is a detail elevation view of the handle of the delivery system of Figure 12 shown in a fired position;

Figure 15 is an elevation view of another pistol grip handle configuration for a delivery system;

Figure 16 is a detail view of the gear train mechanism of the delivery system of Figure 15;

Figure 17 is a detail cutaway elevation view of the delivery system of Figure 15 shown in a starting position;

Figure 18 is a detail cutaway elevation view of the delivery system of Figure 15 shown in a full spring recoil position;

Figure 19 is a detail cutaway elevation view of the delivery system of Figure 15 shown in a fired position;

Figure 20 is an elevation view of a continuous NiTi wire form fastener in pre-deployment position;

Figure 21 is an elevation view of the continuous NiTi wire form fastener of Figure 20 in post-deployment position;

Figure 22 is a bottom elevation view of a straight leg, blunt tip continuous wire form fastener;

Figure 23 is a bottom elevation view of a curved leg, blunt tip continuous wire form fastener;

Figure 24 is a bottom elevation view of a molded tip continuous wire form fastener;

Figure 25 is an elevation view of a continuous NiTi wire form fastener with grounds tips in post-deployment external position;

Figure 26 is an elevation view of a continuous NiTi wire form fastener with grounds tips in post-deployment internal position;

Figure 27 is a bottom elevation view of the continuous NiTi wire form fastener with grounds tips of Figure 26 in post-deployment internal position;

Figure 28 is an elevation view of a radial slide fastener with straight legs and a staple guide;

Figure 29 is an elevation view of the radial slide fastener of Figure 28;

Figure 30 is an elevation view of a radial slide fastener with curved legs;

Figure 31 is an elevation view of a two-part fastening system before installation;

Figure 32 is an elevation view of the two-part fastening system of Figure 31 after installation;

Figure 33 is an elevation view of another two-part fastening system before installation;

Figure 34 is an elevation view of the two-part fastening system of Figure 33 after installation;

Figure 35 is an elevation view of a stand-alone fastener incorporated into a device;

Figure 36 is an elevation view of another stand-alone fastener incorporated into a device;

Figure 37 is an elevation view of another stand-alone fastener incorporated into a device;

Figure 38 is an elevation view of another stand-alone fastener incorporated into a device;

Figure 39 is an elevation view of another stand-alone fastener incorporated into an injection port in a pre-installation position;

Figure 40 is an elevation view of the stand-alone fastener of Figure 39 in a post-installation position;

Figure 41 is an elevation view of a helical coil fastener;

Figure 42 is an elevation view of another helical coil fastener;

Figure 43 is a top view of a horizontal coil fastening system base;

Figure 44 is a side view of the horizontal coil fastening system base of Figure 43;

Figure 45 is a bottom view of the horizontal coil fastening system base of Figure 43;

Figure 46 is an elevation view of a driver tool of a fastening system for the horizontal coil fastening system of Figure 43;

Figure 47 is a detail view of the horizontal coil fastening system base of Figure 43.

Figure 48 is a side view of a closed metal loop fastening system incorporated into a device;

Figure 49 is a top view of device incorporating the closed metal loop fastening system of Figure 48;

Figure 50 is a side view of a two-part snap fit fastening system.

Figure 51 is an elevation view of a another closed metal loop system using curved pins or hooks;

Figure 52 is a side view of the closed metal loop system using the curved pins or hooks of Figure 51 incorporated into a device;

Figure 53 shows top and side views of a curved pin fastening system incorporated into a device;

Figure 54 shows top and side views of another curved pin fastening system incorporated into a device;

Figure 55 shows top and side view of a spring screw fastening system;

Figure 56 shows side view of a folding baseplate with curved fasteners in its open and closed positions;

Figure 57 shows top and side views of rotating hook fasteners incorporated into a device;

Figure 58 is a top elevation view of a rotating disc fastening system with fasteners in pre-deployment position;

Figure 59 is a bottom elevation view of the rotating disc fastening system of Figure 58 with fastener in post-deployment position;

Figure 60 is a bottom view of the rotating disc fastening system of Figure 58 with fasteners in post-deployment position;

Figure 61 is a side view of the rotating disc fastening system of Figure 58 with fasteners partially deployed; and

Figure 62 is an elevation view of the curved fastener of the rotating disc fastening system of Figure 58 showing the axis of rotation.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention encompasses surgical fastening systems wherein an implantable device either contains a plurality of fasteners (e.g. staples) in pre-deployment position, or wherein fasteners are provided adapted to suture holes on the device, or wherein an implantable device may have a detachable housing fitted over the device, wherein the housing contains a plurality of fasteners in pre-deployment position.

The detachable housing and fasteners may be made of various materials known in the art for the manufacture of surgical fasteners and implants. The fasteners may be made of metal, polymer, or other suitable materials. The detachable housing may be made of metal, polymer,

ceramic, or composites; for instance polysulfone, acetyl copolymers, titanium, elastomers and stainless steel are commonly used.

These materials must be biocompatible, i.e., they do not adversely affect the surrounding living environment, and conversely, their performance is not adversely affected by the surrounding living environment. The materials may be inert non-absorbable or biodegradable. Inert materials may be fairly indestructible and maintain their form and function for extended periods of time.

Metals and metal alloys, and particularly titanium and titanium alloys, are used for a great variety of implantable articles for medical applications. All implantable articles suffer from some degree of bio-incompatibility, which may be manifested as tissue inflammation, necrosis, hyperplasia, mutagenicity, toxicity, and other reactions, such as attack by giant cells, leukocytes and macrophages. While titanium and its alloys are generally considered inert when implanted, some biological and biochemical interactions still may occur, and others have found it desirable to provide various coatings on the surface of titanium and titanium alloy implants for certain purposes. The same holds true for many other metals and metal alloys. Thus, the present invention encompasses the use of such coatings on the surface of the fasteners, the removable housing, or the device.

Some of the coatings that may be used in materials to be implanted (whether made of titanium or other materials) include biological agents (such as genetic material or cellular material) or chemical agents (such as anti-proliferation reagents or cell-growth factors) to reduce problems associated with hyperplasia or inflammation. These agents may be mixed with binders such as elastomers or bio-resorbable polymers to the surface of a metal or polymer object.

The fasteners contemplated herein, including staples, are often constructed of wire and thus have a relatively large surface area for their size. Accordingly, methods that allow the addition of biological and biochemical agents to the surface of the implant may be advantageous in minimizing the adverse reactions of body tissues with the implant. These may include coatings applied to stainless steel and titanium alloys (e.g., NiTi alloys) to retard tissue reactions. Such coatings have been based upon stable bio-compatible polymers (such as styrene-isobutylene-styrene (SIBS)) and bio-resorbable polymers, such as polyglycolic acid. In the work known to date, the active chemical or biological agent is mixed with the polymeric coating material, and the agent then elutes from the coating once the implant is placed in the body.

It is also contemplated by the present invention that the fasteners may be made of shape memory alloy (SMA). The driving force for making metal medical devices from shape memory alloys lies in their great resistance to permanent deformation as compared to conventional alloys employed in this application. Alloys used in various medical instruments have relied on stainless steel, high nickel alloys such as Elgiloy™ and titanium based alloys, all of which can be given quite high yield strength through work hardening. Normal metals, even with very high yield strength, cannot sustain strains much greater than 0.2% without suffering a permanent set. Once a bend or kink has been sustained in a device fabricated from one of the above conventional alloys it is virtually impossible to remove. The unusual property of pseudoelasticity exhibited by shape memory alloys such as Au--Cd, Cu--Zn--Al, Ni--Ti and many others makes possible the complete "elastic" recovery of strains as great as 10%. Due to its high recoverable strain and its excellent resistance to corrosion, the shape memory alloy of preference for medical components has been within the Ni--Ti family of alloys.

Shape memory alloys belong to a class which exhibit thermoelastic martensite transformation. The term martensite refers to the crystalline phase which is produced in steels when quenched from a high temperature. The phase which exists at the elevated temperature is referred to as austenite; these terms have been carried over to describe the transformations which occur in shape memory alloys. When a steel has been quenched from the austenitic temperature to martensite, to again form austenite requires heating the structure to quite high temperatures, usually in excess of 1400° F.

By contrast, the thermoelastic shape memory alloys can change from martensite to austenite and back again on heating and cooling over a very small temperature range, typically from 18 to 55° F. The transformation of a shape memory alloy is usually described by a hysteresis curve in which it is shown that on cooling from the austenitic phase, often called the parent phase, martensite starts to form at a temperature designated as M_S and upon reaching the lower temperature, M_F, the alloy is completely martensitic. Upon heating from below the M_F temperature, the martensite starts to revert to the austenitic structure at A_S, and when the temperature designated as A_F is reached, the alloy is completely austenitic. These two phases or crystalline structures have very different mechanical properties: the Young's Modulus of austenite is ~$12x10^6$ psi, while that for martensite is ~$4x10^6$ psi; and the yield strength, which

depends on the amount of cold work the alloy is given, ranges from 28 to 100 ksi for austenite and from 10 to 20 ksi for martensite.

The unique feature of shape memory alloys is their ability to recover deformation. When a shape memory alloy specimen, in its martensitic form is subjected to stress, the strain is accommodated by the growth and shrinkage of individual martensite variants rather than by the mechanisms which prevail in conventional alloys: slip, grain boundary sliding and dislocation motion. When deformed martensite is heated to the austenite finish temperature A_F, the part reverts to its original undeformed state. Thus, for medical implant uses, it is possible to develop a design where the device is stored below body temperature in its unformed shape, and upon insertion into the body, the temperature of the device raises to that of the body, at which point the device reverts to the austenitic structure. In the instant application, the fasteners may be optionally made of an SMA such as NiTi.

It is within the scope of the present invention that such fastening systems as herein described are able to be fastened into bodily tissue in less time than would be required to suture the device into place. In the instance described here (the placement of an access port for a gastric band), the placement and fixation of the fastening system should take no more than five minutes. Additionally, the fixation system is able to be entirely unfastened and removed from the tissue in order to facilitate repositioning of the device, or to remove the implanted device entirely. Such implantation and extraction will not cause increased trauma to the patient, and the fixation system will not cause more adhesions than the traditional suturing method. The average surgeon or other health professional is reliably and consistently able to perform fixation and extraction of the fastening system.

Additionally, during the manufacture of such fixation systems described herein, the size of the fasteners determines the depth into the bodily tissue into which the fasteners will deploy. In the instant case, fixation of an access port should occur at a depth below the device not to exceed 3mm. Also, in such a use, the bodily tissue into which the fasteners are deployed is the fascia. However, it is within the scope of the invention that the bodily tissue to which the device is attached will vary depending on the specific device. Additionally, the attachment of the fastening system into tissue will not cause tissue damage during placement or during body motion; for example, an access port for a gastric band is often attached directly over the rectus

abdominis. Further, the fixation of the device is of equivalent or greater strength to sutures and resists becoming dislodged or disconnected in order to accommodate a long-term implant.

The invention as described herein may be used with any type of implantable device. Examples of such would include internal monitors, ports, pacemakers, therapeutics, drug delivery systems, neurostimulators, orthopedic devices, tendon repair, etc. For ease of explanation, the invention will now be described as depicted in Figures 1-40, wherein the invention is shown used in conjunction with an access port. One of skill in the art will recognize that the present invention may be used with other types of implantable devices, and that the invention may take other forms analogous to those depicted herein.

Additionally, in the accompanying figures, the housing is shaped as a ring, and may accordingly be described as such. However, one of skill in the art will recognize that the shape of the housing is dependent on that of the device, such that the present invention is not limited to devices in which the housing would be circular.

Fig. 1 depicts an access port fastening system according to one embodiment of the present invention. The access port 10 includes a septum 11, which in practice is pierced by a needle to input fluid such as saline into the access port for use with, for example, a hydraulic operated gastric band.

The access port 10 includes a detachable housing 12 which surrounds the outer perimeter of the access port. The housing 12 includes notches or openings 15. The notches house fasteners 14. The notches or openings 15 may take any form necessary to adequately house the fastener 14 while allowing movement of the fastener 14. It is within the scope of the invention that at least three fasteners 14 be present in order to minimize the possibility of movement or dislodgement of the device. As shown in Figs. 1-4, the fasteners 14 are attached to the ring 12 by a perpendicular segment engaged though a hole and thereby pivotally connected to the ring 12. The fasteners 14 have a first position as shown in Figs. 1 and 3 and a second or secured position as shown in Figs. 2 and 4. To move from the first to the second position, the fastener rotates about an axis of the fastener. The notch 15 accommodates this rotation and a small locking tab holds the fastener in position after rotation. In one embodiment, the fasteners 14 may be 2-legged staples. In another embodiment, the staples are rigid, such that they do not deform during the rotation into the fascia of a patient. For such applications conventional metals are

suitable. Furthermore, the staples may be shaped as a "U" or variations thereof, including substantially shaped as:

When in the second position, the fastener 14 is held rigidly in place by a locking tab 16. The formation of the locking tab 16 may be such that upon movement of the fastener 14 from the first to the second position an audible click is heard by the surgeon to indicate that the fastener 14 is fully engaged by the locking tab 16. When in the second position an access port 10 is secured within the housing 12 in the patient by the fasteners 14 which interface with the fascia of the patient. Essentially, the fascia or other bodily tissue is secured between the fasteners 14 and the housing 12 or device 10. Furthermore, the housing 12 may contain pegs (not shown) which engage suture holes (not shown) which surround the perimeter of the device 10.

Figs. 5-8 depict the access port of Fig. 1 and its interaction with an access port delivery system 20. As shown in Fig. 5, the access port delivery system 20 may have a finger depression 25 which is used by the operator to help hold the access port and the delivery system in place and properly aligned.

The delivery system 20 comprises a port cover 21. The port cover 21 houses a plunger 22, a slide pusher 24, and a slide assembly 26. The port cover may be formed in any shape necessary to substantially cover the access port 10.

The plunger 22 provides the operative means for the delivery system 20 and is connected to a firing means which will be described below. Upon actuation of the firing means the plunger 22 moves in the direction of the access port 10. This movement causes the slide pusher 24 to be actuated. The slide pusher 24 transfers the energy of the moving plunger 22 to the slide assembly 26. The slide assembly 26 has a substantially round shape and encircles the access port 10. In other applications, the slide assembly may take a form suitable to the device and housing to be implanted. Upon actuation, the slide assembly 26 is forced in the direction of the access port 10. Alignment tabs 30 assist the alignment of the slide assembly 26. The alignment tabs 30 are attached to the port cover 21 and interact with the access port 10 to ensure proper alignment. The movement of the slide assembly 26 causes beams 28 attached to the slide assembly 26 to act upon the fasteners 14. The imparting of force on the fasteners 14 allows them to rotate in the ring holes (not shown) and to transcribe an arc defined substantially by the notch 15. This rotation coincides with a movement from the first to the second position discussed above. As the

beams 28 continue to be moved towards the access port 10, the fasteners 14 reach the second position and are held in place by the locking tabs 16. In this position the access port 10 is rigidly held in place by the fasteners 14 and their interaction with the fascia or other tissue of the patient.

Fig. 9 shows an access port delivery system complete with a firing means 40. Fig. 10 shows a cross sectional view of the firing means 40 in the starting or loaded position. In this position, the spring 42 is compressed, and a latch 44 that is connected to a rod 46 is secured by a rib 48 to prevent the compressed spring 42 from expanding. The firing means has a trigger 50 connected to a lever 52. As shown in Fig. 10 the spring 42 and rod 46 are in a housing 54.

As shown in Fig. 11, upon application of a predetermined force to the trigger 50, the lever 52 acts on the housing 54. The housing 54 pivots on a fulcrum (not shown), this pivoting action lifts the latch 44 above the end of the rib 48. Upon lifting, the spring force of the compressed spring 42 drives the plunger 22 in the direction of the access port and actuates the mechanism therearound as discussed above. In such a configuration the plunger travel, speed and impact force can be determined to meet the application needs. As tested, the plunger travel was between .25 and .75 in, and can develop up to 50 lb. of force on the plunger, depending upon the spring used in the application.

An alternative to the spring driven mechanism is shown in Fig. 12. Fig. 12 shows a palm grip actuated firing mechanism 60. The palm grip is a very simple design requiring only a single moving part to move the plunger 22. In a first position as shown in Fig, 13, there is a moving handle 61, a stationary handle 62, a pivot point 64, and an actuating tip 66.

In operation the user squeezes on the moving handle 61 forcing it in the direction of the stationary handle 62. This movement forces the actuating tip 66 which is connectively engaged with the moving handle 61 and the pivot point 64 in a direction opposite the direction of movement of the movable handle 61. Through the use of the simple lever action, a comparatively small force applied to the moving handle 61 is amplified through the pivot point 64 and applied by the actuating tip 66 to the plunger 22. The plunger 22 is moved by the actuating tip 66 in the direction of the access port 10 and actuates the mechanism therearound as discussed above. The force produced by the palm grip actuated device is limited only by the strength of the user, as tested the device was capable of producing in excess of 50 lb. of force with a plunger travel of .25 in. Alternatively, a geared mechanism could be produced that could produce equal or greater force although require a greater travel distance for the moving handle

61. The force produced by the device shown in Figs. 12-14 could also be altered as necessary by moving the pivot point 64 nearer the plunger 22 to produce more force, or away from the pivot point to produce less force.

Yet another alternative firing means is shown in Figs. 15-19. The pistol grip firing means 70 includes a trigger 72 having geared teeth 73 located on one end, a gear 74 which meshes with the geared teeth 73, a rack 75 driven by the gear 74, and a spring 76. The rack may also include a means 78 for gripping the plunger 22.

The operative progression is shown in Figs. 17-19. In Fig. 17, the trigger is extended and the spring is under little or no tension. The geared teeth 73 are meshed with corresponding teeth of the gear 74 and with teeth on the rack 75. The plunger 22 is in the extended position. When the trigger 72 is depressed, the geared teeth 73 actuate the gear 74 and in turn cause the rack 75 to compress the spring 76, as shown in Fig. 18. At a predetermined distance the geared teeth 73 no longer engage the gear 74. At this point the gear 74 is free to spin. The stored energy in the spring 76 forces the rack 75 to move toward the plunger 22. The free spinning gear 74 allows the rack 75 to move, which in turn forces the plunger towards the access port 10 and actuates the mechanism therearound as discussed above.

Another feature which may be incorporated into the pistol grip firing means 70 is a lock (not shown), which after the spring 76 is compressed prevents the gear 74 from spinning. Then when desired the operator can release the lock, thereby allowing the spring 76 to expand as discussed above.

As tested, the pistol grip firing means 70 permits the plunger to travel approximately .4 in and can produce in excess of 50 lb. of force. One distinct advantage of this embodiment over, for example, the movable grip device discussed above is the instantaneous deployment having a very high impact speed.

In Fig. 20 a further embodiment of the present invention is shown. The use of NiTi or SMA alloy materials is well known in the medical arts as discussed above. As shown in Fig. 20 NiTi fasteners are shown in a pre-deployment state. The fasteners 14 are continuous and attached to the access port 10 through holes therein. In operation the fasteners 14 are depressed into the fascia of the patient to secure the access port. The NiTi fasteners 14 have the unique ability to change their shape when heated, e.g. to body temperature. As shown in Fig. 21, when

the fasteners are deployed they can change shape to bend under the access port 10 and secure it in place.

In Fig. 22 the fasteners 14 are shown with straight legs 80 in a deployed state. Alternative configurations include curved legs 81 as shown in Fig. 23. Using the curved legs 81, the fascia can be pinched between the fastener and the underside of the access port. A further alternative is shown in Fig. 24 where the tips of the fastener legs 81 are coated with a molded tip 82. The molded tip may be formed in a shape that will assist in piercing the fascia of the patient. This eliminates the need to form the fastener 14 into a shape for piercing. Additionally, the tips 82 may be formed of a bio-absorbable material.

In another embodiment of the present invention, the NiTi fastener can be continuously formed in a ring 84. The use of the ring 84 allows for the fasteners 14 to be formed with a continuous construction. After the ring 84 with the fasteners 14 is formed, the ends of the legs 80 can be ground off to produce individual substantially U-shaped fasteners 14. The ring 84 insures that the fasteners 14 can be inserted as a unit as discussed above, and the grinding of the legs ensures a sufficiently sharp point to pierce the fascia. As shown in Figs. 25 and 27, the legs can be formed and positioned in the ring 84 so that after bending due to heating, the legs 80 face internally to the access port 10 or externally to the access port 10.

Yet another embodiment of the present invention is a two-part fastening system as shown in Figs. 28-34. Fig. 28 shows a guide 90 formed with a plurality of individual fasteners 14. The fasteners 14 are slidable in the guide 90 from a first to a second position. In operation the guide 90 is placed over the access port 10 and aligned with notches 15. The fasteners 14 are formed of a spring like material and shaped to attach to the access port 10. The fasteners 14 are slid from a first position as shown in Fig. 28 to a second position as shown in Fig. 29. The fasteners 14 pierce the fascia and securely hold the access port 14 thereto. As previously described, the fasteners may have straight or curved legs. After the sliding of all of the fasteners from the guide 90 onto the access port 10, the guide may be removed if it is not part of the final implanted device. Alternatively, the guide 90 may also be a permanent part of the implantable device.

A further two-part fastening device includes a pre-formed ring 100 (Fig. 31 and Fig. 32). The ring includes a first securing means 104 for attaching the ring 100 to the fascia. The ring also includes a second securing means 102 for attaching an access port 10 to a secured ring 100. In operation, the ring 100 is placed upon the fascia and then twisted to engage the fascia in the

first securing means 104. The access port 10 is then placed upon the ring 100 and engages the second securing means 102 via holes 106 in the access port. This design allows for positive attachment and re-installation repeatability without disengaging the pre-formed ring.

Fig. 33 and Fig. 34 depict yet another two-part fastening device comprising an applicator 112 and a ring 110 having NiTi fasteners 114. In practice, the ring 110 is inserted into the applicator 112. The applicator 112 is placed over the access port 10 with the fasteners 114 aligned with notches 115 and holes 106. The fasteners 114 are forced through the holes 106 and engage the fascia of the patient upon which the access port 10 rests. Through the heating process, the fasteners 114 change shape and secure the access port to the fascia. After a predetermined time, the applicator can be removed.

Another embodiment of the present invention regards stand alone fasteners. As shown in Figs. 35-38, a variety of designs can be used to secure an access port 10 to the fascia of a patient. The fasteners may incorporate NiTi so that the fasteners change shape upon application of a predetermined amount of heat. These fasteners 14 may be inserted singularly, or as part of a pre-formed ring as discussed above. When inserted singularly, the fasteners 14 may be straight rods or may have some pre-formed shape which may be heightened through the heating process. In Fig. 35, the fastener 14 takes on a curly, pig-tail shape. In Fig. 36 the fastener takes on a substantially C-shaped appearance. Figs. 37 and 38 use U-shaped fasteners 14, the ends of which bend, linearly when heated to form an omega shape as shown in Fig. 37, or perpendicularly to the shape as shown in Fig. 38. These shapes can be chosen as desired for a specific application.

Yet another embodiment of the present invention is shown in Fig. 39. In Fig. 39 the fasteners 14 are slidably installed in the access port 10. This may be accomplished by cold molding of the NiTi fastening system into the device, and allows positive attachment and repeatable re-positioning. Through the use of an installation tool 120, the fasteners are forced through holes in the bottom of the access port 10 and engage the fascia. By installing the fasteners as an integral part of the access port 10, no ring or housing is needed as discussed above for housing the fasteners. The installation tool 120 could be part of a triggering device as disclosed herein. Fig. 40 shows the fastener 14 in the engaged position.

As described above and shown in Figures 1-8, radial pivot fasteners are a simple delivery system, with direct drive. The associated delivery system actuates the pivot for radial entry. The

staple may be stainless steel, titanium, Nitinol or Elgiloy™, or other suitable materials including other metals or plastics. The molded pivot/lock-out system may be designed to snap into the existing suture holes on implantable devices. Additionally, the simple staple shape allows for easy manufacturability. Such a system is self-puncturing, i.e. no pre-puncturing of the bodily tissue, e.g. fascia, is necessary. The curved nature of the staple allows the penetration into the bodily tissue as the staple advances to be predictable; and the pivoting nature of the curved staple generates an easy path through the tissue. Removal of the fastening system requires an extraction tool, and the staples will rotate out of the original entry path with only small resistance from ingrown surrounding tissue. However, the force required to remove the system is adequate to allow the staples to remain locked in position except during a removal procedure.

Continuous wire forms of the fastener system contemplated herein include blunt tips, molded tips, and ground or chopped tips. Blunt tip continuous wire systems, as shown in Figures 20-23 may require pre-puncture for insertion of the blunt tipped wire. The fastener assembly may be manufactured to require the locking feature to retain either the wire form or the overmolded ring. The simple wire form may be made of stainless steel, titanium, Elgiloy™, NiTi or other suitable materials. Removal of the fastener assembly may be done easily due to the blunt ends, which provide minimal tissue damage and trauma. Additionally, the blunt tip reduces the force necessary to remove the assembly. The continuous wire form assembly with molded tips, shown in Figures 20 and 24, does not require pre-puncture of the bodily tissue, and these tips allow for easy entry into the bodily tissue. Further, the chopped or ground blunt end continuous wire form assembly, Figures 25-27, also requires no pre-puncture of the bodily tissue, which also allows for easy entry into the tissue.

The radial slide fastener assembly, depicted herein with flat fasteners (Figures 28 and 29) and curved fasteners (Figure 30), requires a larger entry site than the other fastener assemblies. The fasteners create a path through the bodily tissue that is simple and secure, with added retention in systems utilizing the curved fasteners. Removal of the systems is accomplished with an associated extraction tool that withdraws each fastener from their center position. Alternatively, the fasteners may be manufactured such that removal may be accomplished by lifting the assembly upwards, at which time the fasteners bend to a straightened position, allowing for easy removal.

Fig. 41 depicts a helical coil fastener, which may optionally be utilized with a port that features a tubing connector extending from the center of the base. The corkscrew-type design is mounted to a separate disc which snaps to the port, or may be mounted to the port itself, centered on the base plate. The disc or port is manually affixed to the tissue by rotation of the disc or port, which causes the coil to travel on a helical path through the tissue. In one embodiment, the coil can have a sharpened tip.

A variation of the helical coil fastener is depicted in Fig. 42. Fig. 42 depicts a flat spiral spring that is deflected downward to begin its path through the tissue. The deflecting implement is withdrawn following implantation, allowing the spring to compress during healing. Compression of the spring will reduce the profile of the implanted coil fastener and can reduce the likelihood of pain induction.

Figures 43-47 depict a horizontal coil implantation system. In the horizontal coil system, a metal coil is used horizontally to stitch the port to the tissue. It is well known that such coils can pierce and hold in tissues from their use as mesh tacks in minimally invasive hernia procedures. In this case, the coil travels parallel to the tissue surface instead of perpendicularly, as in the helical coil fasteners described above (see Fig. 55). A small tool is envisioned to aid in driving the coil through the tissue and the mating holes in the base (see Fig. 46). Such holes could be straight holes through a ridge on the bottom of the base (see Figs. 44, 45 and 47), or curved holes molded into a flat-surfaced base. A top view of a base is shown in Fig. 43. It is envisioned that the last hole would be blind, and that the end of the coil would be shaped in a crossbar that could slide over an incline and lock into place, such as into a slot. A variation would feature a path for the coil that curves around the port or base edge, facilitating tool access to the coil. This can also be accomplished by varying the flexibility of the coil. A tube can be added to the tool as a shroud in order to keep the rotating coil from picking up strings of tissue before it travels through the holes.

Figs. 48 to 62 depict various embodiments of a metal suture system. This method of port fixation involves the creation of one or multiple closed metal loops below the port base, by using the base itself as a means to close a loop formed by curved metal members (see, e.g. Figs. 48 and 52). This may be done both with one-piece and two-piece systems, whereby a two-piece system may have a ring that attaches to the port or other device with the system of Fig. 50. One embodiment includes a deflection tool to separate the point of the metal member from contact

with the base allowing the member tip to begin its path downward through the tissue. This can be a circular disc or the port itself. After the point has traveled some distance, the tool is withdrawn, permitting the curved member to then follow a path intersecting with the base. Likewise, another embodiment includes multiple members curved in two planes, such that rotation of the base affects the creating of multiple loops.

An alternate method to achieve such a loop is with a curved pin that is inserted through the base after it is in its intended tissue location, as seen in Figs. 51, 53 and 54. Such a pin by nature follows an arc through the tissue and can easily be directed back to the port base. Such a pin can be made to lock in place after full travel by adding a right angle bend to the pin that snaps into a slot on the base, or other such well-known means (see Fig. 57). A variation on this theme includes an additional straight section on the end of the pin, parallel to the curved section (Fig. 51). A lever arm is used to drive the curved section through the base and to the completion of its intended travel (see Figures 49 and 58-62).

In yet another embodiment, a two-piece system may be used wherein the port attaches to a folding baseplate with sharp, curved extensions (see Fig. 56). The folded plate is placed on the tissue with the extensions pointed toward the tissue. When the baseplate is unfolded (flattened) the extensions are driven 90 degrees in a rotary path (see Fig. 56). The port is then snapped to the baseplate, locking the extensions in position. In one embodiment, the points of the extensions would overlap those from the other half, semi-shielding the points.

Figs. 58-62 illustrate a preferred rotating disc fastener system. After being placed in its desired location, the device to be implanted is secured to the tissue using a plurality of curved pins or hooks 501 (Fig. 62), the tips of which rotate through an arc and are received back in or near the baseplate 510 at the end of their travel. A disc 520 within the baseplate 510 rotates, thereby causing lever arms 525 to push against curved hooks 501, which in turn rotate about their fixed axis in the baseplate through an arc until the rotational travel of the disc stops. In the fully deployed position (Figs. 59 and 60), the tips of hooks 501 are preferably received back in baseplate 510 to form a closed loop. Alternatively, the tips may form less than a closed loop. In either case, it is preferable that the rotating disc 520 locks in place at the end of its travel to lock the hooks in place. One-way flexible locking tabs 527 that engage stops 515 or other locking means may be used to lock the hooks in place by preventing backward rotation of the disc. A deployment tool or delivery system such as that described above with reference to Figures 5-19

may be used to fasten the device in place. The linear motion of the plunger 22 and slide pusher 24 is converted into rotational motion through a transmission using gearing or other well known means.

Although the invention has been particularly shown and described with reference to certain preferred embodiments, and in particular with reference to an access or injection port, it will be readily appreciated by those of ordinary skill in the art that any number of implantable medical devices may be used with the fastening system of the present invention and that various changes and modifications may be made therein without departing from the spirit and scope of the invention.